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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.
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08/951,733 10/16/97 HARRINGTON

L A-433B

HM12/1227

US PATENT OPERATIONS NOA  
MS 101 B AMGEN INC  
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EXAMINER

BUGAISKY, G

ART UNIT	PAPER NUMBER
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1653

16

DATE MAILED:

12/27/99

**Please find below and/or attached an Office communication concerning this application or proceeding.**

**Commissioner of Patents and Trademarks**

<b>Office Action Summary</b>	Application No. <b>08/951,733</b>	Applicant(s) <b>HARRINGTON et al.</b>
	Examiner <b>Gabriel E. Bugaisky</b>	Group Art Unit <b>1653</b>

Responsive to communication(s) filed on Oct 5, 1999

This action is **FINAL**.

Since this application is in condition for allowance except for formal matters, **prosecution as to the merits is closed** in accordance with the practice under *Ex parte Quayle* 35 C.D. 11; 453 O.G. 213.

A shortened statutory period for response to this action is set to expire 3 month(s), or thirty days, whichever is longer, from the mailing date of this communication. Failure to respond within the period for response will cause the application to become abandoned. (35 U.S.C. § 133). Extensions of time may be obtained under the provisions of 37 CFR 1.136(a).

#### Disposition of Claim

Claim(s) 1-35 is/are pending in the application  
Of the above, claim(s) 22-25, 31, and 32 is/are withdrawn from consideration

Claim(s) 1-21, 28-30, and 33 is/are allowed.

Claim(s) 26, 27, 34, and 35 is/are rejected.

Claim(s) \_\_\_\_\_ is/are objected to.

Claims \_\_\_\_\_ are subject to restriction or election requirement.

#### Application Papers

See the attached Notice of Draftsperson's Patent Drawing Review, PTO-948.

The drawing(s) filed on \_\_\_\_\_ is/are objected to by the Examiner.

The proposed drawing correction, filed on \_\_\_\_\_ is  approved  disapproved.

The specification is objected to by the Examiner.

The oath or declaration is objected to by the Examiner.

#### Priority under 35 U.S.C. § 119

Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).

All  Some\*  None of the CERTIFIED copies of the priority documents have been

received.

received in Application No. (Series Code/Serial Number) \_\_\_\_\_.

received in this national stage application from the International Bureau (PCT Rule 17.2(a)).

\*Certified copies not received: \_\_\_\_\_

Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

#### Attachment(s)

Notice of References Cited, PTO-892

Information Disclosure Statement(s), PTO-1449, Paper No(s). 7

Interview Summary, PTO-413

Notice of Draftsperson's Patent Drawing Review, PTO-948

Notice of Informal Patent Application, PTO-152

— SEE OFFICE ACTION ON THE FOLLOWING PAGES —

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### **DETAILED ACTION**

The amendment of 10/5/99 is acknowledged. New claims 34 and 35 have been submitted. Contrary to the statement on page 4, lines 5-7 of the response that only claims 1-21, 26-30 and 33-35 are pending, **claims 22-25 and 31-32 remain withdrawn from consideration.** No amendment directing cancellation of these claims has been presented. Claims currently under consideration are 1-21, 26-30 and 33-35.

#### ***Drawings***

The drawings are objected to by the draftsman, as summarized on the enclosed PTO-948.

#### ***Claim Objections***

The objection to claim 1 is withdrawn, based upon the amendment.

#### ***Claim Rejections - 35 USC § 112***

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 26-27 remain rejected and claims 34-35 are newly rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for the nucleic acids encoding SEQ ID NO: 14 and 20, and catalytically active fragments thereof, and the disclosed mutations of the above gene does not reasonably provide enablement for catalytically active variants. The specification does not enable any person skilled in the art to which it pertains, or with which it is

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most nearly connected, to practice the invention commensurate in scope with these claims. As was stated in the previous Actions, the Examiner has noted the definition of "biologically active" which appears on page 15, lines 33-36 and page 16 lines 1-11, which specifies the active fragment must possess telomerase catalytic activity and have one of several recited properties. The statements of the previous rejections are incorporated here. It is noted that Applicants state one may readily test the variants for catalytic activity by using any of the assays as set forth in the specification. Applicants have not defined the structure of the enzyme sufficiently so to teach where one might make deletions and still reasonably expect to obtain molecules with telomerase catalytic activity. With no guidance as to what regions to make the deletions in, one has been presented with but an invitation to experiment to try to make deletions that then can be tested for catalytic activity.

The rejection of claims 4, 6, 10, 12, 16 and 18 under 35 U.S.C. 112, first paragraph, for scope limited to an isolated nucleic acid encoding the recited polypeptide, is withdrawn, based upon the amendment.

The rejection of claims 1, 7, 13, 19, 27 and claim 33 under 35 U.S.C. 112, second paragraph, as being indefinite, is withdrawn based upon the amendment.

***Conclusion***

Claims 1-2, 28-30 and 33 are allowed.

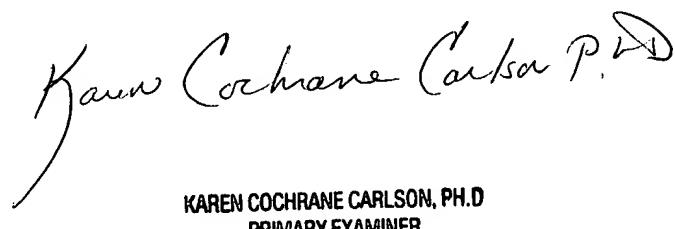
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Any inquiry concerning this communication or earlier communications from the Examiner should be directed to Gabriele E. Bugaisky, Ph.D. whose telephone number is (703) 308-4201. The Examiner can normally be reached from 7:30 AM to 1:30 PM on weekdays.

If attempts to reach the Examiner by telephone are unsuccessful, the Examiner's supervisor, Christopher S. Low, can be reached at (703) 308-2923.

Papers related to this application may be submitted by facsimile transmission. Papers should be faxed to Technology Center 1600 via the PTO Fax Center located in Crystal Mall 1. The faxing of such papers must conform with the notice published in the Official Gazette, 1096 OG 30 (November 15, 1989). The Fax Center number is (703) 308-4242.

Any inquiry of a general nature or relating to the status of this application should be directed to the Technology Center receptionist whose telephone number is (703) 308-0196.



Karen Cochrane Carlson, Ph.D.

KAREN COCHRANE CARLSON, PH.D  
PRIMARY EXAMINER



gab

December 21, 1999